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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,302	06/25/2003	Danilo Porro	2027.594096/RFE	4661

23720 7590 08/22/2006

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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,302	PORRO ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	<i>maf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/2006 and 6/7/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9, 12-19 and 28-33 is/are allowed.
- 6) ☒ Claim(s) 10 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of the papers filed 3/24/2006 and 6/7/2006 in which claim 11 was cancelled, and claims 7, 9, 12-16, 18, 20, 22-24, 27 and 34-35 were amended. Claims 1-10 and 12-35 are pending. Claims 1-6 and 35 are withdrawn. Claims 7-10 and 12-34 are under examination in the instant Office action.

Specification

Applicant's amendment to the specification is acknowledged and found remedial to obviate the objection cited in the prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant's amendment and arguments concerning the rejection of claims 9-10, 18-21, 25-26, 31 and 34, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have

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been carefully considered and found persuasive. **Therefore the rejection is WITHDRAWN.**

Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. **This is a new rejection necessitated by Applicant's amendment.**

Claim 21 recites "[t]he method of claim 20, wherein the coding region encoding LGDH was isolated from *A. thaliana*, the coding region encoding ALO was isolated from *S. cerevisiae*, the coding region encoding AGD was isolated from *A. thaliana*, the coding region encoding ARA was isolated from *S. cerevisiae*, or the coding region encoding RGLO was isolated from *R. norvegicus*" in lines 1-5(emphasis added). Claim 21 is vague and indefinite in that the LGDH and AGD recited in the claims lack proper antecedent basis.

Claim 22 recites "[t]he method of claim 7, wherein the AGD enzyme comprises a signaling peptide" in lines 1-2 (emphasis added). Claim 22 is vague and indefinite in that there is no antecedent basis for "the AGD enzyme." Does Applicant intend one of the enzymes listed in claim 7 such as ARA, ALO or RGLO,

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or does Applicant intend an L-galactono-1,4-lactone dehydrogenase (AGD)?

Similarly, claim 23 recites "[t]he method of claim 7, wherein the AGD enzyme does not comprise a signaling peptide" in lines 1-2 (emphasis added). Claim 23 is vague and indefinite in that there is no antecedent basis for "the AGD enzyme."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's arguments concerning the rejection of claims 12-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been carefully considered and found persuasive. **Therefore the rejection is WITHDRAWN.**

Claims 20 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at

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the time the application was filed, had possession of the claimed invention. **This is a new matter rejection. This is a new rejection necessitated by Applicant's amendment.**

The specification as originally filed does not provide support for the invention as now claimed: "[t]he method of claim 7, wherein the coding region was isolated from *Arabidopsis thaliana*, *S. cerevisiae*, or *Rattus norvegicus*" (claim 20). Nor does the specification provide support for "[a] method of stabilizing ascorbic acid in a medium, comprising: culturing a yeast in the medium, wherein the medium is aerobic" (claim 34). With regard to claim 20, the specification does not mention an ALO, ARA or RGLO enzyme isolated from *A. thaliana*. With regard to claim 34, the specification does not recite the use of an "aerobic" medium in the context of stabilizing ascorbic acid. The specification does not provide sufficient blazemarks nor direction for the instant limitations, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection not necessitated by Applicant's amendment.**

It is apparent that *S. cerevisiae* GRF18U, *S. cerevisiae* strain W3031B, *K. lactis* strain PM6-7A and *Z. bailii* strain ATCC 60483 are required to practice the invention. As such, the strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strains. In the instant case, the recited yeast strains transformed with ARA, ALO or RGLO that are disclosed in the specification do not appear to be obtainable by a repeatable method, nor does it appear the strains are readily available to the public.

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If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a further Non-Final or a Final rejection.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15 of Patent No. 6,630,330 (hereafter Patent '330).

This rejection is maintained for reasons of record, but has been slightly altered in order to accommodate Applicant's amendment.

Although the conflicting claims are not identical (the instant claims are slightly broader in scope as they encompass

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any yeast genus, whereas the reference claims are drawn to *Saccharomyces* yeast strains only), claims 24-26 of the instant application and claims 13-15 of the '330 patent both recite methods for generating ascorbic acid from recombinant yeast encoding ALO and LGDH. The methods comprise the same steps. In both methods at least one of the enzymes is operably linked to a promoter active in the yeast and wherein said promoter is the *S. cerevisiae* TPI promoter.

Response to Arguments

Applicant has deferred a substantive response to the above rejection "until such time as claims are allowed in either the present case or US Patent Application 10/606,302[sic]" (page 14, section 6 of the remarks filed 3/24/2006).

Claims 7 and 11-14 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 12-14 of US Patent Application No. 10/606,300. **This rejection is WITHDRAWN due to Applicant's amendment of the claims.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Roland et al (WO 85/0175; of record). **This rejection is maintained for reasons of record but has been slightly altered in order to accommodate Applicant's amendment.**

Roland et al teach a method of stabilizing ascorbic acid in a medium comprising: culturing a yeast in the medium, wherein the medium is aerobic (see entire document, especially page 14, lines 4-7). Roland et al teach such a method wherein the medium used to culture the yeast is aerobic (see, e.g., Example III; page 4, lines 9-14; and page 38-9, claims 1 and 5). Roland et al teach such a method wherein the ascorbic acid is present in the medium (see, e.g., page 5, 25-31)

Response to Arguments

Applicant argues that Roland et al do not indicate that they were in possession of a method of stabilizing ascorbic acid

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in a medium by culturing yeast in the medium, and that Roland et al therefore do not anticipate claim 34.

Applicant's argument has been carefully considered and is respectfully found unpersuasive. Roland et al need not explicitly indicate that they were in possession of a method of stabilizing ascorbic acid in a medium by culturing yeast in the medium in order to anticipate the claim. The Roland et al reference need only teach the claim limitations, which it does. Roland et al teach the cultivation of yeast in a medium, wherein the medium is aerobic. Roland et al teach that the medium comprises ascorbic acid. Therefore, the Roland et al reference anticipates claim 34.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-8, 28-32 and 34 were rejected under 35 U.S.C. 102(b) as being anticipated by Berry et al (US Patent

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Application No. 2002/0012979 A1; of record). **This rejection is WITHDRAWN due to Applicant's amendment.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant's arguments concerning the rejection of claims 7-9, 11-15, 18, 20-21, 24 & 27-30 under 35 U.S.C. 103(a) as being unpatentable over Lee et al (Applied and Environmental Microbiology 65(10):4685-4687; of record) in view of Suh et al (Molecular Microbiology 30(4):895-903, 1998; of record) have been carefully considered and found persuasive. **Therefore the rejection is WITHDRAWN.**

Allowable Subject Matter

Claims 7-9, 12-19 and 28-33 are allowed.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

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the scanned images of their own application file folder(s) as well as general patent information available to the public.

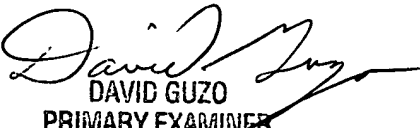
For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

August 17, 2006


DAVID GUZO
PRIMARY EXAMINER